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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/511,008 02/22/00 HAGEMAN

G 20618-000600

EXAMINER

HM22/0705

Patent Group  
Foley Hoag & Eliot LLP  
One Post Office Square  
Boston MA 02109-2170

I.T.O.	
ART UNIT	PAPER NUMBER

1632  
DATE MAILED:

07/05/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

09/511,008

Applicant(s)

HAGEMAN, GREGORY S.

Examiner

Janice Li

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-67 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claims 1-67 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

**DETAILED ACTION**

***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S. C. 121:

- I. Claims 1-12 are drawn to a method for diagnosis of an arterial wall disruptive disorder in a subject comprising detecting markers for macular degeneration in the eye, by physical examination. Classification is to be determined.
- II. Claims 1-10, 12, 14-20, 36, 37, and 67 are drawn to a method and a kit for diagnosis of an arterial wall disruptive disorder in a subject comprising detecting a protein marker associated with a retinal drusen, RPE cell death, an immune-mediated event, such as dendritic associated cytokines, leukocyte surface markers, and a fibrosis associated reaction. Classified in class 435, and subclass 7.1.
- III. Claims 1-10, 12, 13, and 21-35 are drawn to a method for diagnosis of an arterial wall disruptive disorder in a subject comprising detecting a gene marker associated with a retinal drusen, RPE cell death, an immune-mediated event, such as antoantibodies, dendritic associated cytokines, leukocyte surface markers, and a fibrosis associated reaction. Classified in class 435, and subclass 6.
- IV. Claims 38-49 are directed to a method for treatment comprising administering to a subject a pharmaceutical composition, wherein the composition is an anti-inflammatory agent. Classification is to be determined.
- V. Claims 50, 52-57 are directed to a method for identifying an agent by monitoring the effect of the agent to the drusen. Classified as class 424, subclass 9.1.

- VI. Claims 51-56, 58, 59 are directed to a method for identifying an agent by monitoring the changes in drusen-associated molecules. Classified as class 435, subclass 7.1.
- VII. Claims 60, 62 are directed to an animal model for arterial wall disruptive disorder. Classified in class 800, subclass 8.
- VIII. Claim 61 is directed to a transgenic animal predisposed for developing macular degeneration. Classified in class 800, subclass 13.
- IX. Claims 63 and 64 are directed to a transgenic animal carrying a genetically modified homolog of a human AMD-associated gene. Classified in class 800, subclass 13.
- X. Claims 65 and 66 are directed to a transgenic animal carrying a genetically modified drusen-associated gene. Classified in class 800, subclass 13.

2. The inventions are distinct, each from the other because of the following reasons.

Inventions II-VI and I are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are different methods of diagnosis, screening reagents, for treatment of a disease. The different methods have different method steps, different modes of operation, use different starting material, measuring different molecules, and have distinct technical considerations. The differences of the Inventions I-VI are further underscored by their divergent classification and independent search criteria.

Inventions VIII-X and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation,

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different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are different products, i.e. wild-type animals and transgenic animals having different genotypic and phenotypic features, and can be used in different methods, such as screening for an agent or breeding. The differences of the Inventions VII-X are further underscored by their divergent classification and independent search criteria.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and different search criteria, restriction for examination purposes as indicated is proper.

3. This application contains claims directed to the following patentably distinct species of the claimed invention: Inventions II and III are directed to methods detecting different markers as claims 10, 13, 17, 18, 19, 20 and 21 recite. These marker molecules are associated with different physiological events, and requires divergent search criteria. If invention II or III is elected, further election of a species is necessary. Inventions IV is directed to a method of treatment using a pharmaceutical composition. While the claims do not identify a specific composition, they may encompass substantially different materials, such as a chemical compound, a protein agent or a nucleic acid. If Invention IV is elected, further election of a species is necessary. Inventions IX-X are directed to a transgenic animal model targeting different genes, such as recite in claims 64, and 66. If Invention IX or X is elected, further election of a species is necessary.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-37, 38-49, and 63-66 are generic, respectively.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is advised that where a single claim encompasses more than one invention as defined above, upon election of an invention for examination, said claim will only be examined to the extent that it reads upon the elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Q. Janice Li whose telephone number is 703-308-7942. The examiner can normally be reached on 8:30 am - 5 p.m., Monday through Friday.

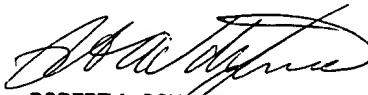
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Karen M Hauda can be reached on 703-305-6608. The fax numbers for the organization where this application or proceeding is assigned are 703-308-8724 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of formal matters can be directed to the patent analyst, Kay Pinsky, whose telephone number is (703) 305-3553.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235. The faxing of such papers must conform to the notice published in the Official Gazette 1096 OG 30 (November 15, 1989).

Q. Janice Li  
Examiner  
Art Unit 1632

QJL  
June 29, 2001

  
ROBERT A. SCHWARTZMAN  
PRIMARY EXAMINER